IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS **Plaintiffs,** **v.** **NORRIS COCHRAN,[*] *in his official capacity as the Acting Secretary of the Department of Health and Human Services,*** **Defendant.**	**CIVIL ACTION NO. 20-738**

MEMORANDUM OPINION

Rufe, J. **February 8, 2021**

Plaintiffs Lynn Oxenberg and Ronald Lewis have brought this action against Defendant Norris Cochran, Acting Secretary of the Department of Health and Human Services, challenging the denial of their claims for Medicare coverage. The issues have been briefed, and the parties filed cross-motions for summary judgment. Defendant then moved to dismiss under Federal Rule of Civil 12(b)(1) for lack of standing under Article III of the United States Constitution. Because Plaintiffs must have standing to proceed with the case, the Court will first rule on Defendant's motion to dismiss. For the reasons stated below, that motion will be granted.

I. BACKGROUND

The facts as alleged in Plaintiffs' complaint are uncontested for purposes of the motion to dismiss. Plaintiffs suffer from glioblastoma multiforme ("GBM"), a particularly lethal form of

[*] Under Fed. R. Civ. P. 25(d), Norris Cochran is substituted as Defendant for former Secretary of the Department of Health and Human Services Alex Azar.

brain cancer. Research has shown that alternating electric fields are effective in disrupting the cell replication of this type of cancer.[1] Treatment based on this research, known as tumor treatment field therapy ("TTFT"), has been shown to be effective in treating GBM.[2] It has been shown to increase the two-year survival rate of GBM patients by more than 38% and nearly triple the five-year survival rate.[3] TTFT is an FDA-approved treatment.

Novocure, Inc. is the manufacturer and sole supplier of the equipment that delivers TTFT, which goes by the brand name "Optune." Novocure rents the Optune device to patients on a monthly basis, and Medicare patients prescribed TTFT submit monthly claims for the use of the device. Patients prescribed TTFT will use the Optune device for the remainder of their lives.

A. Medicare Claims Process

Medicare coverage for the Optune device is provided under Part B, which provides coverage for durable medical equipment.[4] For a device to be covered, it must be "reasonable and necessary;" that is, it must be medically appropriate, safe and effective, and not experimental.[5]

When a claim is denied for not being "reasonable and necessary," a Medicare beneficiary has the right to appeal. There are five levels in the appeal process after an initial denial: 1) the beneficiary can request "redetermination" from the Medicare Contractor, which must be

---

[1] *See, e.g.* Eilon D. Kirson, et al., *Disruption of Cancer Cell Replication by Alternating Electric Fields*, 64 CANCER RESEARCH 3288, 3288–95 (2004), R. at 475–82.

[2] *See, e.g.*, Roger Stupp, et al., *Effect of tumor-treating fields plus maintenance temozolomide vs maintenance temozolomide alone on survival in patients with glioblastoma: a randomized clinical trial*, 318 JAMA 2306, 2306–16 (2017).

[3] *See* Pl.'s Mot. Summ. J. [Doc. No. 12] at 4.

[4] *See* 42 U.S.C. §§ 1395k(a), 1395x(s)(6).

[5] *See, e.g.*, Medicare Program Integrity Manual ("MPIM") § 13.5.4, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/pim83c13.pdf (last accessed Feb. 8, 2021).

performed by a person who did not make the initial decision;[6] 2) if the claim is denied, the beneficiary can request "reconsideration" by a Qualified Independent Contractor ("QIC"), whose panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program;"[7] 3) if the QIC upholds the denial, the beneficiary can appeal to an Administrative Law Judge ("ALJ"), who issues a decision based on the evidence presented at a hearing or otherwise admitted into the administrative record;[8] 4) if the ALJ enters an unfavorable decision and denies the claim, the beneficiary can appeal to the Medicare Appeals Council, which issues the final decision of the Secretary for the purposes of exhaustion;[9] and 5) after a final decision has been made, a beneficiary may file suit in a federal district court to challenge the denial of a claim.[10] A GBM patient may have to go through this entire process repeatedly if TTFT is regularly denied.

B. TTFT Local Coverage Decisions

The Secretary has delegated broad authority in determining whether Medicare covers a particular service to the Centers for Medicare and Medicaid Services ("CMS"). CMS, in turn, contracts with Medicare Administrative Contractors ("MACs") to administer some day-to-day functions, such as making coverage determinations, issuing payments, and developing Local Coverage Determinations ("LCD") for the geographic area it serves.[11]

---

[6] *See* 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940.

[7] 42 C.F.R. § 405.968(c)(1); *see also* 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960.

[8] *See* 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. §§ 405.1000, 405.1002, 405.1042.

[9] *See* 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100.

[10] 42 U.S.C. §§ 1395ff(b), 405(g). A beneficiary may also file in district court if the Council does not respond within a specified time frame. *See* 42 C.F.R. § 405.1132.

[11] *See* 42 U.S.C. § 1395kk-1.

An LCD is an official decision made by a MAC on the Medicare coverage of a particular item or service. It specifies "the circumstances under which the item or service is reasonable and necessary."[12] An LCD is binding on the initial determination and on redetermination, but not on the QIC or ALJ.[13] However, a QIC or ALJ must give LCDs "substantial deference if they are applicable to a particular case."[14] When an ALJ or QIC declines to follow an LCD, they must "explain the reasons why the policy was not followed."[15]

The LCD in effect between October 2015 and September 2019 (the "2015 LCD") provided the following coverage guidelines for TTFT: "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary."[16] Under the 2015 LCD, all requests for coverage for TTFT and the Optune device were initially denied. They were also denied on "redetermination" from the Medicare contractor. This LCD was in effect when Plaintiffs' claims were denied.

On September 1, 2019, the TTFT LCD was revised. The revised LCD permitted coverage for newly diagnosed GBM, and permitted coverage for continued use of TTFT where the clinical benefit is demonstrated and the patient is using the Optune device for an average of 18 hours per

---

[12] MPIM § 13.5.4.

[13] *See* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

[14] 42 C.F.R. § 405.968(b)(2); *see also* 42 C.F.R. § 405.1062(a).

[15] 42 C.F.R. § 405.1062(b); *see also* 42 C.F.R. § 405.968(b)(3).

[16] Local Coverage Determination No. L34823, Effective Oct. 1, 2015, https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=34823:3 (last accessed Feb. 8, 2021).

day.[17] According to Novocure, the coverage criteria under the revised LCD "is generally similar to Optune's commercial coverage criteria for newly diagnosed GBM."[18]

C. Procedural History

1. Plaintiff Lynn Oxenberg

Plaintiff Lynn Oxenberg was diagnosed with GBM in November 2017. After surgery and chemo-radiation, Ms. Oxenberg was prescribed TTFT and the Optune device. She submitted monthly claims for coverage for the Optune device, and each claim was initially denied under the 2015 LCD. She appealed these denials through four separate appeals.[19] Although the underlying facts were the same in each appeal, three of ALJs approved coverage and one ALJ denied coverage. The ALJs approving coverage rejected the 2015 LCD because of the "overwhelming" medical literature establishing the effectiveness of TTFT.[20] The favorable decisions became final, and Ms. Oxenberg timely appealed the decision denying coverage.

2. Plaintiff Ronald Lewis

Plaintiff Ronald Lewis was diagnosed with GBM in early 2018. After surgery and chemo-radiation, he was prescribed TTFT and the Optune device. Mr. Lewis's monthly claims were also initially denied under the 2015 LCD. He appealed the decisions through two separate

---

[17] Sept. 1, 2019 Revision to Local Coverage Determination No. L34823, R. 132–53. The TTFT LCD was revised again on January 1, 2020. The current LCD is substantially similar to the Sept. 1, 2019 revision. *See* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=34823 (last accessed Feb. 8, 2021).

[18] Businesswire, *Medicare Releases Final Local Coverage Determination Providing Coverage of Optune for Newly Diagnosed Glioblastoma* (July 18, 2019), https://www.businesswire.com/news/home/20190718005355/en/ (last accessed Feb. 8, 2021).

[19] Medicare sends notice of denials to beneficiaries on "a quarterly/90-day mailing cycle," and an appeal is generally made of all denials occurring within those three months. Medicare Claims Processing Manual § 21.10, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c21.pdf (last accessed Feb. 8, 2021).

[20] *See, e.g.*, R. at 30–31. The ALJ denying coverage determined that even if the LCD was outdated, an ALJ lacked the authority to review the validity or categorically reject an LCD. *Id*. at 71–72.

appeals. One ALJ found in Mr. Lewis's favor and another did not.[21] The favorable decision became final, and Mr. Lewis timely appealed the unfavorable decision.

3. Plaintiffs' appeal of denials of coverage

After properly exhausting administrative remedies, Plaintiffs brought this action under 42 U.S.C. § 405(g), appealing the decisions denying their claims. Plaintiffs argue that because the favorable decisions are final, the Secretary should be collaterally estopped from issuing denials on the grounds the favorable final decisions reject.

II. LEGAL STANDARD

Under Rule 12(b)(1), a complaint must be dismissed if the court lacks subject matter jurisdiction to hear the claim.[22] Federal courts are courts of limited jurisdiction and under Article III of the Constitution, a federal court only has the power to adjudicate "cases" or "controversies."[23] "[T]he irreducible constitutional minimum of standing consists of three elements:" (1) the plaintiff must have suffered an injury in fact; (2) the injury must be fairly traceable to the challenged conduct of the defendant; and (3) the injury is likely to be redressed by a favorable judicial decision.[24] The party asserting standing has the burden of establishing these elements.[25]

---

[21] The favorable decision found that it was "appropriate to depart from the [2015 LCD] based upon evidence that was not available at the time the LCD was written." *Id.* at 739. The unfavorable decision found that the ALJ lacked the authority to consider the validity of the 2015 LCD and therefore could not depart from it. *See id.* at 2829.

[22] *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012).

[23] U.S. Const., art. III, § 2.

[24] *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016), *as revised* (May 24, 2016) (citations and quotations omitted).

[25] *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

III. DISCUSSION

"To establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'"[26] For an injury to be "concrete," it must be "real, and not abstract,"[27] and "a risk of real harm may satisfy the requirement of concreteness."[28]

Three other district courts have considered nearly identical cases involving the denial of claims covering TTFT under the 2015 LCD, and each case was dismissed for lack of standing.[29] Those courts found no injury-in-fact because the plaintiffs were not financially liable for the denial of coverage and they were unable to show more than a "mere[] hypothetical or conjectural" risk of any future harm.[30] Similarly, Plaintiffs have not shown any injury-in-fact. They have not shown any tangible financial injury, any legitimate risk of future harm, or any statutorily created injury.

1. Plaintiffs have not suffered a tangible economic injury

Despite the denied claims, Plaintiffs received and continue to receive the necessary TTFT treatment. Under the ALJ decisions, the supplier Novocure—not Plaintiffs—was financially responsible for the denied coverage. The ALJ for Ms. Oxenberg's denial held that "[t]he supplier is responsible for knowing that the disputed services were not medically reasonable and

---

[26] *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560).

[27] *Id.* (quotations and citations omitted).

[28] *Kamal v. J. Crew Grp., Inc.*, 918 F.3d 102, 115 (3d Cir. 2019).

[29] *See Pehoviack v. Azar*, No. 20-0661, 2020 WL 4810961, at *3 (C.D. Cal. July 22, 2020); *Komatsu v. Azar*, No. 20-0280, 2020 WL 5814116, at *3 (C.D. Cal. Sept. 24, 2020); *Prosser v. Azar*, No. 20-0194, 2020 WL 6266040, at *1 (E.D. Wis. Oct. 21, 2020).

[30] *Komatsu*, 2020 WL 5814116, at *2; *see also* Pehoviack, 2020 WL 4810961, at *3 ("Plaintiff has not directly experienced any injury stemming from the MAC Denial, and the potential consequences she discusses in her Opposition remain speculative.").

necessary. Thus, the supplier remains responsible for the non-covered charges."[31] The ALJ for Mr. Lewis's denial held that "[t]he Beneficiary neither knew, nor reasonably should have been expected to know, that any of the services would not be covered by Medicare. The liability of the Beneficiary is waived . . . . However, . . . the Provider is liable for the non-covered charges."[32] Neither Plaintiff has suffered any tangible economic harm from their denials.

2. Plaintiffs have not shown a risk of future harm

Plaintiffs argue that because Novocure may decide to no longer cover denied treatment, they face an actual or imminent threat of harm.[33] But there is no evidence in the record that Novocure will in fact shift the financial risk of a denial to Plaintiffs, and "allegations of hypothetical, future injury are insufficient to establish standing."[34]

An Advanced Beneficiary Notice ("ABN") is a form signed by a beneficiary explaining that Medicare will most likely deny coverage for a specific service and detailing the specific reason why.[35] A supplier such as Novocure must first provide a beneficiary with an ABN before financial liability for a denial of coverage can be shifted onto the beneficiary. Despite the denials of coverage, Novocure has not required either Plaintiff to sign an ABN, and there is no indication that Novocure plans to do so in the future.

Furthermore, Plaintiffs' denials were under the 2015 LCD, which rejected coverage for TTFT as a matter of course. The 2015 LCD is no longer in effect. Under the current LCD,

---

[31] R. at 72.

[32] *Id.* at 2830.

[33] Pls.' Opp. Mot. to Dismiss [Doc. No. 34] at 9–11.

[34] *Reilly v. Ceridian Corp.*, 664 F.3d 38, 42 (3d Cir. 2011).

[35] *See* 42 C.F.R. § 411.404(b).

continued coverage for TTFT is "reasonable and necessary" where the patient is adhering to the treatment and deriving a benefit from it. The record does not show that any coverage has been denied under the current LCD. It also does not suggest that Plaintiffs' continued coverage would not meet the current LCD's requirements. Indeed, one ALJ noted that "[Ms. Oxenberg] would fit within the very specific and limited parameters set out in the [current LCD],"[36] and Plaintiffs have stated that "[o]ther than the cases at issue, each of Plaintiffs' claims has eventually been paid."[37]

For Plaintiffs to be held financially liable for future TTFT treatment, numerous events must come to pass. They must be denied coverage under the current LCD, that denial must be upheld on appeal, and Plaintiffs must be required to sign an ABN. Plaintiffs must then be denied coverage again, and that denial must be upheld on appeal. Plaintiffs' risk of future financial harm is not "certainly impending," as is required to constitute an injury-in-fact.[38]

3. Plaintiffs have not shown a statutorily created injury

Plaintiffs contend that they have suffered an injury-in-fact through the deprivation of a substantive statutory right.[39] "Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of statute."[40] Additionally, the Supreme Court has

---

[36] *See* R. at 14.

[37] Pls.' Opp. Mot. to Dismiss [Doc. No. 34] at 2.

[38] *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (citations and quotations omitted). However, if some of these preconditions were to come to pass, Plaintiffs may file a new suit.

[39] *See* Pls.' Opp. Mot. to Dismiss [Doc. No 34] at 4–7.

[40] *Warth v. Seldin*, 422 U.S. 490, 514 (1975).

noted that "Congress is well positioned to identify intangible harms that meet minimum Article III requirements."[41]

But "Congress cannot erase Article III's standing requirements."[42] A plaintiff will not have constitutional standing just because a statute "grants a person a statutory right and purports to authorize that person to sue to vindicate that right." [43] "[E]ven in the context of a statutory violation," there must still be a cognizable injury.[44] The Third Circuit has interpreted this to mean that a statutory violation that does not cause an actual harm must create a material risk of the harm that the statute was intended to prevent.[45]

Plaintiffs have alleged an intangible injury—that the supplier and not Medicare was financially responsible for their treatment. They argue that this is a statutory violation of Medicare because Congress created an entitlement to Medicare benefits.[46] But as discussed above, under the facts of this case, Plaintiffs' denials have not caused any tangible financial harm or created any material risk of future harm. Plaintiffs have therefore alleged only "a 'bare procedural violation, divorced from any concrete harm,' that cannot 'satisfy the injury-in-fact requirement of Article III.'"[47]

---

[41] *Spokeo*, 136 S. Ct. at 1549.

[42] *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997).

[43] *Spokeo*, 136 S. Ct. at 1549.

[44] *Id.*

[45] *See Kamal*, 918 F.3d at 112–13 (citations and quotations omitted) ("If the violation does not present a material risk of harm to that underlying interest, however, a plaintiff fails to demonstrate concrete injury.").

[46] *See* Pls.' Opp. Mot. To Dismiss [Doc. No 34] at 5 (citing 42 U.S.C. § 1395k(a)).

[47] *Long v. Se. Pennsylvania Transportation Auth.*, 903 F.3d 312, 325 (3d Cir. 2018) (quoting *Spokeo*, 136 S. Ct. at 1549). *See also* Pozzuolo *v. Portfolio Recovery Assocs., LLC*, 371 F. Supp. 3d 217, 224 (E.D. Pa. 2019) (citations and quotations omitted) (holding that plaintiff lacked standing because "[e]ven though there was a violation of [the statute], [plaintiff] cannot show actual harm or a material risk of harm. By his own admission, he was not hurt as a result of receiving this letter.").

Plaintiffs also argue a statutory injury because Medicare creates a "Mulligan," or do-over, where "the Secretary will still pay the claim if the beneficiary neither knew nor should have known that the claim would be rejected."[48] Plaintiffs argue that because of the denials, they have lost their "Mulligan," and this is a concrete injury-in-fact. But Plaintiffs still do not face financial exposure in the absence of an ABN. Even if this type of loss would be sufficient, a beneficiary's "Mulligan" is only lost when the conditions of the new denial were "comparable" to the earlier denial.[49] As discussed above, Plaintiffs' denials were under the 2015 LCD and all new claims will be reviewed under the current LCD. The Secretary has asserted that the adoption of the current LCD is a significant change and "[i]t is highly unlikely that an ALJ would deem the plaintiffs to have knowledge that their TTFT claims would be denied under the [current] LCD, given a denial in different circumstances under the [2015] LCD."[50]

4. Plaintiffs have no concrete stake in the outcome of this action

Plaintiffs' situation is comparable to that of the plaintiffs in *Thole v. U. S. Bank N.A.*[51] In *Thole*, the plaintiffs brought a claim against the fiduciaries of their retirement plan alleging mismanagement. But the plan only provided fixed monthly benefits, no matter the fiduciaries' performance. Because of this, if the plaintiffs were to lose their lawsuit, "they would still receive

---

Plaintiffs argue that other district courts have found that denial of a Medicare entitlement creates a "concrete injury," even when there is no financial harm. *See* Pls.' Opp. Mot. to Dismiss [Doc. No. 34] at 5–6 (collecting cases). But the cases cited by Plaintiffs "are inconsistent with modern standing precedent of the Supreme Court because they rely on a notion that standing may be founded on no more than an abstract 'entitlement' right created by statute without focus on whether a plaintiff has sustained a practical, concrete injury from the claimed violation of the statutory right." *Hull v. Burwell*, 66 F. Supp. 3d 278, 284 (D. Conn. 2014).

[48] Pls.' Opp. Mot. to Dismiss [Doc. No. 34] at 8–9; *see also* 42 U.S.C. § 1395pp(a).

[49] 42 U.S.C. § 1395pp(a)(2).

[50] Def.'s Reply Supp. Mot. to Dismiss [Doc. No. 36] at 8.

[51] 140 S. Ct. 1615 (2020).

the exact same monthly benefits that they are already slated to receive, not a penny less," and if they were to win their lawsuit, "they would still receive the exact same monthly benefits that they are already slated to receive, not a penny more."[52] The Supreme Court held that under these circumstances, the plaintiffs had "no concrete stake" in the outcome of the action and lacked Article III standing.[53]

Here, if Plaintiffs were to win this lawsuit, Medicare would pay for their treatment, and if they were to lose, Novocure would pay for their treatment. No matter the outcome, Plaintiffs' treatment will have been covered. Just as in *Thole*, Plaintiffs lack a concrete stake in the outcome of the suit and lack standing.[54]

IV. CONCLUSION

The Court is sympathetic to Plaintiffs' plight. Plaintiffs suffer from a lethal form of brain cancer, and under the 2015 LCD, coverage for their necessary, life-extending treatment was denied. At a time when Plaintiffs should have been concentrating on their treatment and spending time with loved ones, they instead had to repeatedly file and litigate appeals from denials of coverage. Unfortunately, Plaintiffs' harm is not cognizable under Article III and not redressable by this Court. Defendant's motion to dismiss will be granted and this action will be dismissed without prejudice.[55] An order will be entered.

---

[52] *Id.* at 1619.

[53] *Id.*

[54] *See also Wheeler v. Travelers Ins. Co.*, 22 F.3d 534, 538 (3d Cir.1994) (holding that plaintiff lacked standing because "[plaintiff] never has had anything to gain from this lawsuit" where a private insurance company denied a claim for healthcare expenses already paid on her behalf by Medicare and she was obligated to remit any payment she received to Medicare).

[55] *See Cottrell v. Alcon Labs.*, 874 F.3d 154, 164 n.7 (3d Cir. 2017) ("Because the absence of standing leaves the court without subject matter jurisdiction to reach a decision on the merits, dismissals 'with prejudice' for lack of standing are generally improper.").